Supplement to

INFORMATION LETTER

Not for Publication — NATIONAL CANNERS ASSOCIATION — For Members Only

No. 1814 — Washington, D. C. — February 11, 1961

FOOD ADDITIVE REGULATION

(Federal Register of Jan. 31, 1961)

Title 21—FOOD AND DRUGS

Chapter I—Food and Drug Administration, Department of Health, Education, and Welfare

SUBCHAPTER B—FOOD AND FOOD PRODUCTS

PART 121—FOOD ADDITIVES

Subpart B — Substances Generally Recognized as Safe Under the Conditions and With the Limitations Prescribed

LISTS OF SUBSTANCES

On February 2 and August 4, 1960, there were published in the FEDERAL REGISTER (25 F.R. 880, 7332) two lists of substances which the Commissioner of Food and Drugs proposed to list in Subpart B, above identified, as safe for use in foods, subject to the limitations specified. Each of the Commissioner's proposals provided an opportunity for the filing of comments.

After careful consideration of the views and comments filed, some of which are accepted in whole or in part, and some of which are rejected, the Commissioner has concluded that the substances named in the above-cited proposals may properly be added to the list of substances generally recognized as safe. Accordingly, the proposals are adopted as published, except:

1. Minor changes in nomenclature have been made.

2. "Chlorophyll (extracted from plants without change in chemical structure)," under the category "Nutrients," is removed from the list published August 4, 1960, because extraction of chlorophyll from green plant tissues requires a procedure in which it is virtually impossible to remove the chlorophyll in the natural state and thereby permit the addition of chlorophyll per se, to food.

3. Torula yeast, dried, has been removed from the list published February 2, 1960, because the use and processing of "torula yeast, dried" may result in preparations containing a level of folic acid not generally recognized as safe as outlined in the statement of general policy and interpretation on the status of folic acid under the provisions of the Federal Food, Drug, and Cosmetic Act (21 CFR 3.42). Under such conditions, it is concluded that torula yeast, dried, cannot be considered generally recognized as safe as defined in the statute.

It is the opinion of the Commissioner that preparations of yeast, for use in dietary supplements, and which contain folic acid are food additives requiring appropriate regulations prescribing the conditions under which they may be safely used.

These lists are incorporated in § 121.101. *Therefore, it is ordered,* That paragraph (d) of that section be revised to read as set forth below.

This action is taken pursuant to the authority provided in the Federal Food, Drug, and Cosmetic Act (secs. 409, 701; 52 Stat. 1055, as amended; 72 Stat. 1785; 21 U.S.C. 348, 371) and delegated to the Commissioner by the Secretary of Health, Education, and Welfare (25 F.R. 8625).

§ 121.101 Substances generally recognized as safe under the conditions and with the limitations prescribed.

* * * * * * *

(d) Substances that are generally recognized as safe for their intended use within the meaning of section 409 of the act are as follows:

Product	Tolerance	Limitations or restrictions
(1) ANTICAKING AGENTS		
Aluminum calcium silicate	2 percent	In table salt.
Calcium silicate	5 percent	In baking powder.
Calcium silicate	2 percent	In table salt.
Magnesium silicate	do	Do.
*Sodium aluminosilicate (sodium silicoaluminate).	do	
*Sodium calcium aluminosilicate, hydrated (sodium calcium silicoaluminate).	do	
Tricalcium silicate	do	Do.
(2) CHEMICAL PRESERVATIVES		
Ascorbic acid		
Ascorbyl palmitate		
Benzoic acid	0.1 percent.	
Butylated hydroxyanisole	Total content of antioxidants not over 0.02 percent of fat or oil content, including essential (volatile) oil content of food.	
Butylated hydroxytoluene	do	
Calcium ascorbate		
Calcium propionate		
*Calcium sorbate		
Caprylic acid		In cheese wraps.
Dilauryl thiodipropionate	Total content of antioxidants not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food.	
Erythorbic acid		
Gum guaiac	0.1 percent (equivalent antioxidant activity 0.01 percent).	In edible fats or oils.
*Methylparaben (methyl-p-hydroxybenzoate).	0.1 percent	
Nordihydroguaiaretic acid	Total content of antioxidants not over 0.02 percent of fat or oil content including essential (volatile) oil content of the food.	
Potassium bisulfite		Not in meats or in food recognized as source of vitamin B_1.
Potassium metabisulfite		Do.
Potassium sorbate		
Propionic acid		
Propyl gallate	Total content of antioxidants not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food.	
*Propylparaben (propyl p-hydroxybenzoate).	0.1 percent	
Sodium ascorbate		
Sodium benzoate	0.1 percent	
Sodium bisulfite		Not in meats or in foods recognized as a source of vitamin B_1.
Sodium metabisulfite		Do.
Sodium propionate		
Sodium sorbate		Do.
Sodium sulfite		
Sorbic acid		
*Stannous chloride	0.0015 percent calculated as tin	Do.
Sulfur dioxide		
Thiodipropionic acid	Total content of antioxidants not over 0.02 percent of fat or oil content, including essential (volatile) oil content of the food.	
Tocopherols		
(3) EMULSIFYING AGENTS		
Cholic acid	0.1 percent	Dried egg whites.
Desoxycholic acid	do	Do.
Diacetyl tartaric acid esters of mono- and diglycerides from the glycerolysis of edible fats or oils.		
Glycocholic acid	0.1 percent	Do.
Mono- and diglycerides from the glycerolysis of edible fats or oils.		
Monosodium phosphate derivatives of mono- and diglycerides from the glycerolysis of edible fats or oils.		
Propylene glycol		
Ox bile extract	0.1 percent	Do.
Taurocholic acid (or its sodium salt)	do	Do.
(4) NONNUTRITIVE SWEETENERS		
*Ammonium saccharin		
Calcium cyclamate (calcium cyclohexyl sulfamate).		
Calcium saccharin		
*Magnesium cyclamate (magnesium cyclohexyl sulfamate).		
*Potassium cyclamate (potassium cyclohexyl sulfamate).		
Saccharin		
Sodium cyclamate (sodium cyclohexyl sulfamate).		
Sodium saccharin		

*Substances added from February 2 and August 4, 1960, proposed lists.

Product	Tolerance	Limitations or restrictions
(5) NUTRIENTS AND/OR DIETARY SUPPLEMENTS [1]		
*Alanine (L- and DL-forms)		
*Arginine (L- and DL-forms)		
Ascorbic acid		
*Aspartic acid (L- and DL-forms)		
*Biotin		
Calcium carbonate		
*Calcium citrate		
*Calcium glycerophosphate		
Calcium oxide		
Calcium pantothenate		
Calcium phosphate (mono-, di-, tribasic).		
*Calcium pyrophosphate		
Calcium sulfate		
Carotene		
*Choline bitartrate		
*Choline chloride		
Copper gluconate	0.005 percent	
Cuprous iodide	0.01 percent	In table salt as a source of dietary iodine.
*Cysteine (L- form)		
*Cystine (L- and DL- forms)		
Ferric phosphate		
Ferric pyrophosphate		
Ferric sodium pyrophosphate		
*Ferrous gluconate		
*Ferrous lactate		
Ferrous sulfate		
*Glycine (aminoacetic acid)		In animal feeds.
*Histidine (L- and DL- forms)		
*Inositol		
Iron, reduced		
*Isoleucine (L- and DL-forms)		
*Leucine (L- and DL-forms)		
*Linoleic acid (prepared from edible fats and oils and free from chick-edema factor).		
Lysine (L- and DL-forms)		
*Magnesium oxide		
*Magnesium phosphate (di-, tribasic)		
*Magnesium sulfate		
*Manganese chloride		
*Manganese citrate		
*Manganese gluconate		
*Manganese glycerophosphate		
*Manganese hypophosphite		
*Manganese sulfate		
*Manganous oxide		
*Mannitol	5 percent	In special dietary foods.
*Methionine		Animal feeds.
*Methionine hydroxy analog and its calcium salts.		Do.
Niacin		
Niacinamide		
D-Pantothenyl alcohol		
*Phenylalanine (L- and DL-forms)		
Potassium chloride		
*Potassium glycerophosphate		
Potassium iodide	0.01 percent	In table salt as a source of dietary iodine.
*Proline (L- and DL-forms)		
Pyridoxine hydrochloride		
Riboflavin		
Riboflavin-5-phosphate		
*Serine (L- and DL-forms)		
Sodium pentothenate		
Sodium phosphate (mono-, di-, tribasic).		
Sorbitol	7 percent	In foods for special dietary use.
Thiamine hydrochloride		
Thiamine mononitrate		
*Threonine (L- and DL-forms)		
Tocopherols		
a-Tocopherol acetate		
*Trypotophane (L- and DL-forms)		
*Tyrosine (L- and DL- forms)		
*Valine (L- and DL-forms)		
Vitamin A		
Vitamin A acetate		
Vitamin A palmitate		
Vitamin B_{12}		
Vitamin D_2		
Vitamin D_3		
*Zinc sulfate		
*Zinc gluconate		
*Zinc chloride		
*Zinc oxide		
*Zinc stearate (prepared from stearic acid free from chickedema factor)		
(6) SEQUESTRANTS [2]		
Calcium acetate		
Calcium chloride		
Calcium citrate		
Calcium diacetate		
Calcium gluconate		
Calcium hexametaphosphate		
Calcium phosphate, monobasic		
Calcium phytate		
Citric acid		
Dipotassium phosphate		
Disodium phosphate		
Isopropyl citrate	0.02 percent	
Monoisopropyl citrate		
Potassium citrate		
Sodium acid phosphate		
Sodium citrate		
Sodium diacetate		
Sodium gluconate		
Sodium hexametaphosphate		
Sodium metaphosphate		
Sodium phosphate (mono-, di-, tribasic).		
Sodium potassium tartrate		
Sodium pyrophosphate		
Sodium pyrophosphate, tetra		
Sodium tartrate		
Sodium thiosulfate	0.1 percent	In salt.
Sodium tripolyphosphate		
Stearyl citrate	0.15 percent	
Tartaric acid		
(7) STABILIZERS		
*Acacia (gum arabic)		
Agar-agar		
*Ammonium alginate		
*Calcium alginate		
Carob bean gum (locust bean gum)		
Chondrus extract (carrageenin)		
*Ghatti gum		
Guar gum		
*Potassium alginate		
*Sodium alginate		
*Sterculia gum (karaya gum)		
*Tragacanth (gum tragacanth)		
(8) MISCELLANEOUS AND/OR GENERAL PURPOSE FOOD ADDITIVES		
Acetic acid		
*Adipic acid		Buffer and neutralizing agent.
Aluminum ammonium sulfate		
Aluminum potassium sulfate		
Aluminum sodium sulfate		
Aluminum sulfate		
Ammonium bicarbonate		
Ammonium carbonate		
Ammonium hydroxide		
Ammonium phosphate (mono- and dibasic).		
*Ammonium sulfate		

*Substances added from February 2 and August 4, 1960, proposed lists.

[1] Amino acids listed may be free, hydrochloride salt, hydrated, or anhydrous form, where applicable.

[2] For the purpose of this list, no attempt has been made to designate those sequestrants that may also function as chemical preservatives.

Product	Tolerance	Limitations or restrictions
(S) MISCELLANEOUS AND/OR GENERAL PURPOSE FOOD ADDITIVES—con.		
*Beeswax (yellow wax)		
*Beeswax, bleached (white wax)		
*Bentonite		
Butane		
Caffeine	0.02 percent	In cola-type beverages.
Calcium carbonate		
Calcium chloride		
Calcium citrate		
Calcium gluconate		
Calcium hydroxide		
Calcium lactate		
Calcium oxide		
Calcium phosphate (mono-, di-, tribasic)		
Caramel		
Carbon dioxide		
Carnauba wax		
Citric acid		
*Dextrans (of average molecular weight below 100,000)		
Ethyl formate	0.0015 percent	As fumigant for cashew nuts.
*Glutamic acid		Salt substitute.
*Glutamic acid hydrochloride		Do.
Glycerin		
Glyceryl monostearate		
Helium		
*Hydrochloric acid		Buffer and neutralizing agent.
*Hydrogen peroxide		Bleaching agent.
Lactic acid		
*Lecithin		
Magnesium carbonate		
Magnesium hydroxide		
Magnesium oxide		
Magnesium stearate		As migratory substance from packaging materials when used as a stabilizer.
*Malic acid		
*Methylcellulose (U.S.P. methylcellulose, except that the methoxy content shall not be less than 27.5 percent and not more than 31.5 percent on a dry-weight basis).		
Monoammonium glutamate		
*Monopotassium glutamate		
Nitrogen		
*Nitrous oxide		Propellant for certain dairy and vegetable-fat toppings in pressurized containers.
Papain		
Phosphoric acid		
Potassium acid tartrate		
Potassium bicarbonate		
Potassium carbonate		
Potassium citrate		
Potassium hydroxide		
*Potassium sulfate		
Propane		
Propylene glycol		
*Rennet (rennin)		
*Silica aerogel (finely powdered microcellular silica foam having a minimum silica content of 99.5 percent).		Component of anti-foaming agent.
Sodium acetate		
Sodium acid pyrophosphate		
Sodium aluminum phosphate		
Sodium bicarbonate		
Sodium carbonate		
Sodium citrate		
*Sodium carboxymethylcellulose (the sodium salt of carboxymethylcellulose not less than 99.5 percent on a dry-weight basis, with maximum substitution of 0.95 carboxymethyl groups per anhydroglucose unit, and with a minimum viscosity of 25 centipoises for 2 percent by weight aqueous solution at 25° C.).		
*Sodium caseinate		
Sodium citrate		
Sodium hydroxide		
*Sodium pectinate		
Sodium phosphate (mono-, di-, tribasic)		
Sodium potassium tartrate		
Sodium sesquicarbonate		
Sodium tripolyphosphate		
*Succinic acid		
Sulfuric acid		
Tartaric acid		
Triacetin (glyceryl triacetate)		
Triethyl citrate	0.25 percent	Dried egg whites.

*Substances added from February 2 and August 4, 1960, proposed lists.

Effective date. This order shall become effective on the date of publication in the FEDERAL REGISTER.

(Sec. 409(c), 72 Stat. 1786; 21 U.S.C. 348(c))

Dated: January 18, 1961.

[SEAL]

GEO. P. LARRICK,
Commissioner of Food and Drugs.

[F.R. Doc. 61-723; Filed, Jan. 30, 1961; 8:45 a.m.]

Supplement to

INFORMATION LETTER

Not for Publication — NATIONAL CANNERS ASSOCIATION — For Members Only

No. 1814 — Washington, D. C. — February 11, 1961

COLOR ADDITIVE REGULATION

(from Federal Register of Jan. 24, 1961)

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Food and Drug Administration

[21 CFR Part 8]

COLOR ADDITIVES

Proposed Definitions and Procedural and Interpretative Regulations

The Commissioner of Food and Drugs, in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (secs. 701, 706, 52 Stat. 1055, 74 Stat. 399; 21 U.S.C. 371, 376) and pursuant to the authority delegated to him by the Secretary of Health, Education, and Welfare (25 F.R. 8625) proposes the promulgation of the following regulations with respect to color additives, and hereby offers an opportunity to all interested persons to present their views in writing to the Hearing Clerk, Department of Health, Education, and Welfare, 330 Independence Avenue SW., Washington 25, D.C., within 30 days from the date of publication of this notice in the FEDERAL REGISTER. Comments may be accompanied by a memorandum or brief, and it is requested that all comments be filed in quintuplicate.

Subpart A—Definitions and Procedural and Interpretative Regulations

Sec

Subpart B—General Specifications and General Restrictions for Color Additives for Use in Foods, Drugs, and Cosmetics

Subpart C—Listing of Color Additives for Food Use Subject to Certification [Reserved] [1]

Subpart D—Listing of Color Additives for Food Use Exempt to Certification [Reserved]

Subpart E—Listing of Color Additives for Drug Use Subject To Certification [Reserved]

Subpart F—Listing of Color Additives for Drug Use Exempt to Certification [Reserved]

Subpart G—Listing of Color Additives for Cosmetic Use Subject to Certification [Reserved]

[1] The provisional listings of color additives in §§ 8.501 et seq., will be effective until the regulations in Subparts C–H, inclusive, shall have been promulgated.

Subpart H—Listing of Color Additives for Cosmetic Use Exempt From Certification [Reserved]

AUTHORITY: §§ 8.1 to 8.101 issued under secs. 701, 706, 52 Stat. 1055, as amended; 74 Stat. 399; 21 U.S.C. 371, 376.

Subpart A—Definitions and Procedural and Interpretative Regulations

§ 8.1 Definitions and interpretations.

(a) "Secretary" means the Secretary of Health, Education, and Welfare.

(b) "Department" means the Department of Health, Education, and Welfare.

(c) "Commissioner" means the Commissioner of Food and Drugs.

(d) "Act" means the Federal Food, Drug, and Cosmetic Act, as amended.

(e) "Color Certification Branch" means the unit established within the Food and Drug Administration located in the Bureau of Biological and Physical Sciences, charged with the responsibility for the development of color methods and the mechanics of the certification procedure hereinafter described, and including the examination of samples of color additives subject to certification.

(f) "Color additives" includes any substance not exempted under section 201(t) of the act, which, when added or applied to a food, drug, or cosmetic or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting a color thereto. This includes all diluents. The term also includes substances capable of imparting color to a container for food, drugs, or cosmetics if the customary or reasonably foreseeable handling or use of the container may reasonably be expected to result in the color being transmitted to the contents of the package or any part thereof, whether or not such transfer is intended by the manufacturer of the container, or of the food, drug, or cosmetic. Food ingredients such as cherries, green or red peppers, chocolate, and orange juice which contribute their own natural color when mixed with other foods are not regarded as "color additives"; but where a food substance such as beet juice is deliberately used as a color, as in pink lemonade, it is a "color additive." Food ingredients as authorized by a definition and standard of identity prescribed by regulations pursuant to section 401 of the act are "color additives," where the ingredients are specifically designated in the definitions and standards of identity as permitted for use for coloring purposes. An ingredient of an animal feed which by its action through the biological process of the animal is capable of imparting color to the meat, milk, or eggs of the animal, whether or not the ingredient has additional nutritive functions, is a color additive and is not exempt from the requirements of the statute. A substance applied to the human body which results in coloring is a "color additive." For the purposes of this part, the term "color" includes black, white, and intermediate grays, but substances including migrants from packaging materials which do not contribute any color apparent to the naked eye are not "color additives."

(g) For a substance otherwise meeting the definition of "color additive" to be exempt from section 706 of the act, on the basis that it is used (or intended to be used) solely for a purpose or purposes other than coloring, the material must:

(1) If a food additive, have been approved for the intended use; or

(2) Be demonstrated to be safe if being added to a drug or cosmetic; and

(3) Be used in a way that any color imparted is clearly unimportant insofar as the appearance, value, marketability, or consumer acceptability is concerned. (It is not enough to warrant exemption if conditions are such that the primary purpose of the material is other than to impart color.)

(h) The exemption that applies to a pesticide chemical, soil or plant nutrient, or other agricultural chemical, where its coloring effect results solely from its aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil, applies only to color developed in such product through natural physiological processes such as enzymatic action. If the pesticide chemical, soil or plant nutrient, or other agricultural chemical itself acts as a color, or carries as an ingredient a color, and because of this property colors the produce of the soil, it is a "color additive" and is not exempt.

(i) "Safe" means that there is convincing evidence that establishes with reasonable certainty that no harm will result from the intended use of the color additive.

(j) The term "straight color" means a color additive listed in Subparts C, D, and E of this part, and includes lakes and such substances as are permitted by the specifications for such color.

(k) The term "mixture" means a color additive made by mixing two or more straight colors, or one or more straight colors and one or more diluents.

(l) The term "lake" means a straight color extended on a substratum by adsorption, coprecipitation, or chemical combination that does not include any combination of ingredients made by simple mixing process.

(m) The term "diluent" means any component of a color additive mixture that is not of itself a color additive and has been intentionally mixed therein.

(n) The term "substratum" means the substance on which the pure color in a lake is extended.

(o) The term "pure color" means the color contained in a color additive, exclusive of any intermediate or other component, or of any diluent or substratum contained therein.

(p) The term "batch" means a homogeneous lot of color additive produced by an identified production operation, which is set apart and held as a unit for the purpose of obtaining certification of such quantity.

(q) The term "batch number" means the number assigned to a batch by the person who requests certification thereof.

(r) The term "lot number" means an identifying number or symbol assigned to a batch by the Food and Drug Administration.

(s) The term "area of the eye" means the area enclosed within the circumference of the supra-orbital ridge and the infra-orbital ridge, including the eyebrow, the skin below the eyebrow, the eyelids and the eyelashes, and conjunctival sac of the eye, the eyeball, and the soft areolar tissue that lies within the perimeter of the infra-orbital ridge.

(t) The term "mixed oxides" means the sum of quantities of aluminum, iron, calcium, and magnesium (in whatever combination they may exist in a color additive) calculated as aluminum trioxide, ferric oxide, calcium oxide, and magnesium oxide.

(u) The term "package" means the immediate container in which a color has been packed for shipment or delivery. If the package is then packed in a shipping carton or other protective container, such container shall not be considered to be the immediate container. In the case of color mixtures for household use containing less than 5 percent pure color, when two or more containers of 1 ounce each or less, each containing a different color, are distributed as a unit, the immediate container for such unit shall be considered to be the package as defined in this section.

(v) The term "hair dye" means an article (bearing or containing a color additive) that is prominently labeled with the name "hair dye," that is intended for use solely as a hair dye, and that alters the color of the hair when applied to the hair under conditions of use prescribed in the labeling. It does not include color shampoos, rinses, tints, and similar dual-purpose cosmetics which alter the color of the hair.

§ 8.2 Related substances.

(a) Different color additives may cause similar or related pharmacological or biological effects, and, in the absence of evidence to the contrary, those that do so will be considered to have additive toxic effects.

(b) Food additives may also cause pharmacological or biological effects similar or related to such effects caused by color additives, and, in the absence of evidence to the contrary, those that do so will be considered as having additive toxic effects.

(c) Pesticide chemicals may also cause pharmacological or biological effects similar or related to such effects caused by color additives, and, in the absence of evidence to the contrary, those that do so will be considered to have additive toxic effects.

(d) In establishing tolerances for color additives, the Commissioner will take into consideration, among other things, the amount of any common component permitted in other color additives, in food additives, and in pesticide chemical residues as well as the similar biological activity (such as cholinesterase inhibition) produced by such substance.

§ 8.3 Color additives in standardized foods.

(a) Where a petition is received for issuance or amendment of a regulation establishing a definition and standard of identity for a food under section 401 of the act, which proposes the inclusion of a color additive in the standardized food, the provisions of the regulations in this part shall apply with respect to the information that must be submitted with respect to the safety of the color additive (if such information has not previously been submitted and safety of the color additive for the intended use has not been already established), and the petition must show also that the use of the color additive in the standardized food would be in conformance with section 401 of the act or with the terms of a temporary permit issued under § 3.12 of this chapter.

(b) If a petition for a definition and standard of identity contains a proposal for a color additive regulation, and the petitioner fails to designate it as such, the Commissioner, upon determining that the petition includes a proposal for a color additive regulation, shall so notify the petitioner and shall thereafter proceed in accordance with the regulations in this part.

(c) A regulation will not be issued allowing the use of a color additive in a food for which a definition and standard of identity is established, unless its issuance is in conformance with section 401 of the act or with the terms of a temporary permit issued under § 3.12 of this chapter. When the contemplated use of such additive complies with the terms of a temporary permit, the color additive regulation will be conditioned on such compliance and will expire with the expiration of the temporary permit.

§ 8.4 Petitions proposing regulations for color additives.

(a) Any interested person may propose the listing of a color additive for use in or on any food, drug, or cosmetic. Such proposal shall be made in a petition in the form prescribed in paragraph (c) of this section. The petition shall be submitted in triplicate. If any part of the material submitted is in a foreign language, it shall be accompanied by an accurate and complete English translation. The petitioner shall state the post-office address in the United States to which published notices or orders issued or objections filed pursuant to section 706 of the act may be sent.

(b) Pertinent information may be incorporated in, and will be considered as part of, a petition on the basis of specific reference to such information submitted to and retained in the files of the Food and Drug Administration. However, any reference to unpublished information furnished by a person other than the applicant will not be considered unless use of such information is authorized in a written statement signed by the person who submitted the information. Any reference to published information offered in support of a color additive petition should be accompanied by reprints or photostatic copies of such references.

(c) Petitions shall include the following data and be submitted in the following form:

(Date)

Name of petitioner ----------
Post-office address ----------
Name of color additive and proposed use ----

Commissioner of Food and Drugs,
Food and Drug Administration,
Department of Health, Education, and Welfare,
Washington 25, D.C.

Dear Sir:

Petitioner submits this pursuant to section 706(b)(1) of the Federal Food, Drug, and Cosmetic Act requesting listing by the Commissioner of the color additive ---------- as suitable and safe for use in or on ---------- subject to the conditions that ----------

[Petitioner may propose a listing for general use in food, drugs, or cosmetics or, if such general listing is not believed suitable and safe, the petitioner shall describe the conditions under which he believes the additive can be safely used and for which it will be suitable. These conditions may include tolerance limitations, specifications as to the manner in which the additive may be added or used, and directions and other labeling or packaging safeguards that should be applied. The level of use proposed should not be higher than reasonably required to accomplish the intended color effect.]

Attached hereto in triplicate and constituting a part of this petition are the following:

A. The name and all pertinent information concerning the color additive, including chemical identity and composition of the color additive, its physical, chemical, and biological properties, and specifications prescribing its component(s) and identifying and limiting the reaction byproducts and other impurities.

The petition shall contain a description of the chemical and physical tests relied upon to identify the additive and shall contain a full description of the methods used in, and the facilities and controls used for, the production of the color additive. These shall establish that it is a substance of reproducible composition. Alternative methods and controls and variations in methods and controls, within reasonable limits, that do not affect the characteristics of the substance or the reliability of the controls may be specified.

The petition shall supply a list of all substances used in the synthesis, extraction, or other method of preparation, regardless of whether they undergo chemical change in the process. Each substance should be identified by its common or usual name and its complete chemical name, using structural formulas when necessary for specific identification. If any proprietary preparation is used as a component, the proprietary name should be followed by a complete quantitative statement of composition. Reasonable alternatives for any listed substance may be specified.

If the petitioner does not himself perform all the manufacturing, processing, and packing operations for a color additive, the petition shall identify each person who will perform a part of such operations and designate the part.

The petition shall include stability data, and, if the data indicate that it is needed to insure the identity, strength, quality, or purity of the additive, the expiration period that will be employed as well as any packaging and labeling precautions needed to preserve stability.

B. The amount of the color additive proposed for use and the color effect intended to be achieved, together with all directions, recommendations, and suggestions regarding the proposed use, as well as specimens of the labeling proposed for the color additive. If the additive results or may reasonably be expected to result from its use in packaging material, the petitioner shall show how this may occur and what residues may reasonably be anticipated.

Typewritten or other draft-labeling copy will be accepted for consideration of the petition, provided a statement is made that final printed labeling identical in content to the draft copy will be submitted as soon as available and prior to the marketing of the color additive.

If the color additive is one for which a tolerance limitation is required to assure its safety, the level of use proposed should be no higher than the amount reasonably required to accomplish the intended physical or other technical effect, even though the safety data may support a higher tolerance. If the safety data will not support the use of the amount of the color additive reasonably needed to accomplish the desired color effect, the requested tolerance will not be established. Petitioners are expected to propose the use of color additives in accordance with sound color chemistry.

C-1. A description of practicable methods to determine the pure color and all intermediates, subsidiary colors, and other components of the color additive.

2. A description of practicable methods to determine the amount of the color additive in any raw, processed, and/or finished food, drug, or cosmetic in which use of the color additive is proposed. (The tests proposed shall be those that can be used for food, drug, or cosmetic control purposes and can be applied with consistent results by any properly equipped laboratory and trained personnel.)

3. A description of methods for identification and determination of any substance found in or on such food, drug, or cosmetic because of the use of the color additive. (If it is the petitioner's view that any such method would not be needed, under the terms of the section 706(b)(5)(A)(iv), a statement shall be submitted in lieu of methods as to the basis for such view.)

D. Full reports of investigations made with respect to the safety of the color additive.

(A petition will be regarded as incomplete unless it includes full reports of adequate tests reasonably applicable to show whether or not the color additive will be safe for its intended use. The reports ordinarily should include detailed data derived from appropriate animal and other biological experiments in which the methods used and the results obtained are clearly set forth. The petition shall not omit without explanation any data that would influence the evaluation of the safety of the color additive).

E. Complete data which will allow the Commissioner to consider, among other things, the probable consumption of, and/or other relevant exposure from the additive and of any substance formed in or on food, drugs, or cosmetics because of such additive; and the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in the diet, including, but not limited to food additives and pesticide chemicals for which tolerances or exemptions from tolerances have been established.

F. Proposed tolerances and other limitations on the use of the color additive, if tolerances and limitations are required in order to insure its safety. A petitioner may include a proposed regulation.

G. If exemption from batch certification is requested, the reasons why it is believed such certification is not necessary.

H. If submitting a petition to alter an existing regulation issued pursuant to section 706(b) of the act, full information on each proposed change that is to be made in the

original regulation must be submitted. The petition may omit statements made in the original petition concerning which no change is proposed. A supplemental petition must be submitted for any change beyond the variations provided for in the original petition and the regulation issued on the basis of the original petition.

I. The prescribed fee of $------ for admitting the color additive to listing is enclosed (unless there is an advance deposit adequate to cover the fee).

Yours very truly,

(Petitioner)

By ---

(Indicate authority)

(d) The petitioner will be notified of the date on which his petition is filed; and an incomplete petition, or one that has not been submitted in triplicate, will be retained but not filed. A petition shall be retained but shall not be filed if any of the data listed in the above form are lacking or are not set forth so as to be readily understood or if the prescribed fee has not been submitted. The petitioner will be notified in what respects his petition is incomplete.

(e) The petition must be signed by the petitioner or by his attorney or agent, who is a resident of the United States, or by an authorized official.

(f) The data specified under the several lettered headings should be submitted on separate sheets or sets of sheets, suitably identified. If such data have already been submitted with an earlier application, the present petition may incorporate it by specific reference to the earlier petition.

§ 8.5 Notification of filing of petition.

(a) Except where the petition involves a new drug, the Commissioner, within 15 days after receipt, will notify the petitioner of acceptance or nonacceptance of a petition, and if not accepted the reasons therefor. If accepted, the date of the notification letter sent to petitioner becomes the date of filing for the purposes of section 205(d) (1) of the act. If the petitioner desires, he may supplement a deficient petition after being notified regarding deficiencies. If the supplementary material or explanation of the petition is deemed acceptable, petitioner shall be notified. The date of such notification becomes the date of filing. If the petitioner does not wish to supplement or explain the petition and requests in writing that it be filed as submitted, the petition shall be filed and the petitioner so notified. The date of such notification becomes the date of filing. Where the petition involves a new drug, notification to the petitioner will be made within 30 days.

(b) The Commissioner will cause to be published in the FEDERAL REGISTER within 30 days from the date of filing of such petition a notice of the filing, the name of the petitioner, and a brief description of the proposal in general terms. A copy of the notice will be mailed to the petitioner when the original document is signed.

§ 8.6 Publication of regulation.

The Commissioner will forward for publication in the FEDERAL REGISTER, within 90 days after filing of the petition (or within 180 days if the time is extended as provided for in section 706(d) (1) of the act):

(a) A regulation listing in Subpart C, D, E, F, G, or H of this part the color additive on the appropriate list or lists as provided under section 706(b) (1).

(1) Such a regulation may list the color additive for use generally in or on food, drugs, or cosmetics as the case may be, or may prescribe the conditions under which the color additive may be safely used (including, but not limited to, specifications as to the particular food, drug, or cosmetic or classes of food, drugs, or cosmetics in or on which such additive may be used; the maximum quantity that may be used or permitted to remain in or on such food, drug, or cosmetic; the manner in which such additive may be added to or used in or on such food, drug, or cosmetic; and any directions or other labeling or packaging requirements for such additives deemed necessary to assure the safety of such use).

(2) Such regulations shall list the color additive only for the use or uses for which it has been found suitable and for which it may safely be employed. Alternatively, the Commissioner shall by order deny the petition, and notify the petitioner of such order and the reasons therefor.

(b) Whenever the Commissioner finds that batch certification is not necessary for the protection of the public health he will, by order, exempt the color additive from the certification procedure. In determining whether certification of a color additive is necessary, the Commissioner will consider the composition of the additive, its manufacturing process, possible impurities, its toxic potential, control and analytical procedures necessary to assure compliance with the listing specifications, and the variability of its composition.

§ 8.7 Samples.

The Commissioner may request samples of the color additive, articles used as components thereof, or of the food, drug, or cosmetic in which the additive is proposed to be used, at any time while a petition is under consideration. The Commissioner shall specify in the request for a sample of the color additive, or articles used as components thereof, or of the food, drug, or cosmetic in or on which the additive is proposed to be used, a quantity deemed adequate to permit tests of analytical methods to determine quantities of the color additive present in products for which it is intended to be used or adequate for any study or investigation reasonably required with respect to the safety of the additive or the physical or technical effect it produces. The data used for computing the 90-day limit for the purposes of section 706(d) (1) of the act shall be moved forward 1 day for each day, after the mailing date of the request, taken by the petitioner to submit the sample. If the information or sample is requested a reasonable time in advance of the 180 days, but is not submitted within such 180 days after filing of the petition, the petition will be considered withdrawn without prejudice.

§ 8.8 Extension of time for studying petition.

If the Commissioner determines that additional time is needed to study and investigate the petition, he shall by written notice to the petitioner extend the 90-day period for not more than 180 days after the filing of the petition.

§ 8.9 Confidentiality of petition.

Data in a petition regarding any method or process entitled to protection as a trade secret will be held confidential and not revealed, unless it is necessary to do so in the record of an administrative hearing preliminary to possible judicial proceedings under section 706 of the act. Data in the petition will not be revealed to persons other than the petitioner and persons engaged in the enforcement of the act beyond that which is necessary to comply with section 706(d) (1) (notice of the regulation proposed) and 706(b) (1) (order acting on the petition).

§ 8.10 Deception as a basis for refusing to issue regulations.

The Commissioner shall refuse to issue a regulation listing a color additive, if in his judgment the data before him show that such proposed use would promote deception of the consumer or would result in misbranding or adulteration within the meaning of the act. Such a finding shall be by order published in the FEDERAL REGISTER subject to the filing of objections and a request for a hearing by adversely affected parties.

§ 8.11 Allocation of color additives.

Whenever, in the consideration of a petition or a proposal to list a color additive or to alter an existing listing, the data before the Commissioner fail to show that it would be safe to list the color additive for all the uses proposed or at the levels proposed, the Commissioner will notify the petitioner and other interested persons by publication in the FEDERAL REGISTER that it is necessary to allocate the safe tolerance for the color additive among the competing needs. This notice shall call for the presentation of data by all interested persons on which the allocation can be made in accordance with section 706(b) (8) (A), (B), and (C) of the act. The time for acting upon the petition shall be stayed until such data are presented, whereupon the time limits shall begin to run anew. As promptly as possible after presentation of the data, the Commissioner will, by order, announce the allocation and the tolerance limitations.

§ 8.12 Advisory committee on the application of the anti-cancer clause.

(a) Any person who will be adversely affected by any action or proposed action applying the anti-cancer clause, may at any time, before or within 30 days after, the publication of the Commissioner's order taking such action, request the referral of the matter to an advisory committee for a report and recommendations. Such request shall be made in writing to the Commissioner

and shall be accompanied by an advance deposit for fees prescribed by § 8.50.

(b) The Commissioner may, at any time, upon his own initiative refer any such matter to an advisory committee for a report and recommendations. In case the Commissioner on his own initiative deems it necessary to refer a proposal to an advisory committee, he shall, in writing, so inform the person filing the petition, if any there be.

§ 8.13 Appointment of advisory committee.

(a) Whenever the referral of a petition or proposal to an advisory committee is requested, or the Commissioner otherwise deems such referral necessary, the Commissioner will request the National Academy of Sciences to select qualified experts willing to serve on the advisory committee. All such experts shall have had sufficient training and experience in biology, medicine, physiology, toxicology, pharmacology, veterinary medicine, or other appropriate science to qualify them on the subject matter to be referred to them. The Commissioner will request the National Academy of Sciences, when it furnishes the names of such experts, to supply a biographical sketch showing the background of their experience and their connection, if any, with academic and commercial institutions.

(b) Each advisory committee shall consist of not less than three experts qualified in the subject matter to be referred to the committee and of adequately diversified professional background. The Commissioner may specify a larger number to serve. He shall appoint one member of the committee as chairman, and the chairman shall be the spokesman of the committee for receiving and forwarding reports and other functions of the committee.

(c) The Commissioner shall appoint the experts so selected and fix their compensation at not to exceed $75.00 a day for each day or part thereof spent in committee meetings and in traveling to and from committee meetings held outside the city of their residence, plus necessary traveling and subsistence expenses while the experts are serving away from their places of residence. Subsistence expenses shall not exceed $25.00 per day.

§ 8.14 Procedure for advisory committee.

(a) The Commissioner shall submit to the chairman of the committee the petition, if any there be; all pertinent data on which he based the issuance, amendment, or repeal of any regulation in question; and other such relevant, reliable information as is available. When the Commissioner submits a proposal to an advisory committee, he shall inform the petitioner, if any there be, and furnish him with copies of material other than the petition that is furnished the committee. The chairman of the committee shall acknowledge receipt of the information and readiness of the committee to act. The date of receipt of such information shall be considered the beginning of the period allowed for consideration by the committee. Copy of this acknowledgment shall be forwarded to the petitioner, if any there be, by the chairman of the committee.

(b) A secretariat to the advisory committees will be established by the Commissioner. The secretariat shall furnish members of the committee with copies of the proposal or petition and any data received by the chairman. If the chairman of the committee believes that a meeting of the committee is necessary before making a recommendation, he shall so advise the Commissioner. Such meetings shall be held in Washington, D.C., or at such other place as the Commissioner shall furnish a suitable meeting place for the committee. If a meeting is held, the secretariat shall keep the minutes and provide clerical assistance.

(c) As soon as practicable, the advisory committee shall make an independent study of the data, and not later than 60 days after receipt of the proposal or petition (unless the time has been extended as provided in paragraph (d) of this section), the chairman shall certify to the Commissioner the report and recommendations of the committee, including any minority report, together with all underlying data and a statement of the reasons or basis for the recommendations, and shall return the petition or proposal. The report will include copies of all material considered by the committee, except that in the case of scientific literature readily available in scientific libraries proper reference may be made to it instead of furnishing actual copies. A copy of the report of the advisory committee will be supplied to any person who has filed a petition or requested the referral to the advisory committee.

(d) If at any time within 60 days the chairman believes that the advisory committee needs more time, he shall so inform the Commissioner in writing, in which case he shall make the certification contemplated by section 706(b)(5)(C)(ii) of the act within the additional 30 days. The Commissioner shall in turn notify the petitioner.

(e) Within 30 days after receipt of the committee report, the Commissioner shall confirm or modify any order theretofore issued by him or shall issue an order acting on the proposal if no order has been issued.

(f) The chairman of the committee, after consultation with the committee members, will inform the National Academy of Sciences of the committee's opinion as to the member who may best represent the committee at a hearing, if one occurs.

(g) More than one petition or proposal may be handled by a committee concurrently.

(h) A person who has filed a petition or who has requested the referral of a proposal to the advisory committee in accordance with the provisions of this section, as well as representatives of the Department of Health, Education, and Welfare, shall have a right to consult with the committee in connection with the petition or proposal. Such persons shall notify the chairman and if practicable make appointments through him. The report of the committee shall show the names of persons other than committee members discussing proposals or petitions with the committee. Except for discussions with authorized persons the committee shall not disclose data originating with a petitioner prior to publication of a regulation.

§ 8.15 Condition for certification.

(a) When the Commissioner cannot conclude from the information before him that there is a basis for exempting a color additive from the requirement of batch certification, he will so order by appropriate listing in Subpart C, E, or G of this part. The Commissioner's order shall state in detail the specifications that shall be met by the color additive.

(b) Each order shall state a period of time, not exceeding 90 days, after which use of a color additive subject to batch certification but not from a batch certified by procedure prescribed in this section would result in adulteration of the product in which it is used.

§ 8.16 Revocation of exemption from certification.

If information becomes available to the Commissioner that a color additive that has been granted exemption from certification should not, for the protection of the public health, be so exempted, such exemption will be canceled forthwith by a notice published in the FEDERAL REGISTER.

§ 8.17 Listing and exemption from certification on the Commissioner's initiative.

Where a petition for a regulation to list a color additive has not been received and the Commissioner has available facts which demonstrate that a color additive should be listed and/or that certification procedure is not necessary in order to protect the public health, he may list such color additive by appropriate regulation and listing in Subpart D, F, or H of this part, and he may exempt the color additive from certification.

§ 8.18 Request for exemption from certification.

A manufacturer, packer, or distributor of a color additive that has not been exempted from the certification procedure by order of the Commissioner may make formal objections and request an order providing such exemption. Such a request shall be accompanied by full facts on which such a request is based. The request may furnish reasonable grounds for the desired finding including specifically why such certification is not necessary for the protection of the public health.

§ 8.19 Procedure for filing objections to regulations.

(a) Objections under sections 706(d) and 203(d)(2)(C) of the act shall be submitted in quintuplicate to the Hearing Clerk of the Department and shall be accompanied by a filing fee as specified in § 8.50. Each objection to a provision of the regulation shall be separately numbered.

(b) A statement of objections shall not be accepted for filing if:

(1) It fails to establish that the objector is adversely affected by the regulation; or

(2) It does not specify with particularity the provisions of the regulation to which objection is taken; or

(3) It does not state reasonable grounds for each objection raised. Grounds which it is reasonable to conclude are capable of being established by reliable evidence at the hearing and which if proved would call for changing the provisions specified in the objections will be deemed reasonable grounds.

(4) The fee is not submitted.

(c) If the statement of objections may not be filed, the Commissioner shall inform the objector of the reasons.

§ 8.20 Notice of public hearing.

If the objections and statement filed by any person, when they are considered with the record in the proceeding (including any reply to the objections that the petitioner may have filed), show that the person filing the objections will be adversely affected and that the grounds stated in support of the objections are reasonable, the Commissioner shall cause to be published in the FEDERAL REGISTER a notice reciting the objections and announcing a public hearing to receive evidence on them. The notice shall designate the place where the hearing will be held, specify the time within which appearances must be filed, and specify the time (not earlier than 30 days after the date of the notice) when the hearing will start. The hearing shall convene at the place and time announced in the notice, but thereafter it may be moved to a different place and may be continued from day to day or recessed to a later day without other notice than announcement thereof by the presiding officer at the hearing.

§ 8.21 Hearing procedure.

Public hearings will be conducted in accordance with the rules provided therefor in Part 2 of this chapter.

§ 8.22 Request for certification.

A request for certification of a batch of color additive shall:

(a) Be addressed to the Color Certification Branch.

(b) Be prepared in the maner set forth in paragraph (i) of this section.

(c) Be submitted in duplicate.

(d) Be signed by a responsible officer of the manufacturer requesting certification of the batch. In the case of a foreign manufacturer, the request for certification must be signed by a responsible officer of such firm, and, by his agent who resides in the United States.

(e) Show the name and post-office address of the actual manufacturer in case such manufacturer is not the person requesting certification of the batch.

(f) Be accompanied by the fee prescribed in § 8.50 unless the manufacturer has established with the Food and Drug Administration an advance deposit to be used for prepayment of such fees. In no case shall the Commissioner consider a request for certification of a batch of color additive if the fee accompanying such request is less than that required by § 8.50 or if such fee exceeds the amount held in the advance deposit account of the manufacturer submitting such request for certification.

(g) Be accompanied by the sample prescribed in § 8.23 consisting of:

(1) Four ounces in the case of straight colors and lakes.

(2) Two ounces in the case of repacks and mixtures.

A sample accompanying a request for certification must be submitted under separate cover and should be addressed to the Color Certification Branch.

(h) The name of a color additive shall be given in the following manner:

(1) The name of straight color additives shall be the name of the color as listed in Subparts C, D, E, F, G, or H of this part.

(2) The name of a lake shall be the name derived in the maner described in Subparts C, D, E, F, G, or H of this part.

(3) The name of a mixture shall be the name given to such mixture by the manufacturer.

(4) The name of a repack shall be the name described in subparagraph (1), (2), or (3) of this paragraph, whichever is applicable.

(i) The form for submission of the application shall be one of the following, depending upon whether the color additive is a straight color, a lake, a repack, or a previously certified color additive, or a mixture of color additives:

(1) *Request for certification of a batch of straight color additive.*

Date .....

Color Certification Branch,
Food and Drug Administration,
Department of Health, Education, and Welfare,
Washington 25, D.C.

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of straight color additive.

Name of color .....
(As listed in Subpart C, E, or G)
Batch number .....
(Manufacturer's number)
Batch weighs ..... pounds
Batch manufactured by .....
..... at .....
(Name and address of actual manufacturer)
How stored pending certification .....
.....
(State conditions of storage, with kind and size of containers, location, etc.)
Certification requested of this color for use in
.....
(State proposed uses)
Required fee, $..... (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 8.23 and is accurately representative thereof.

(Signed)
By .....
.....
(Title)

(2) *Request for certification of a batch of color additive lake.*

Date .....

Color Certification Branch,
Food and Drug Administration,
Department of Health, Education, and Welfare,
Washington 25, D.C.

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive lake.

Name of color .....
Batch number .....
(Manufacturer's number)
Batch weighs ..... pounds
Name of color used .....
Quantity ..... pounds
Lot number .....
(When certification of the lake for use in foods is requested)
Precipitant used .....
Substratum used .....
Quantity ..... pounds
Batch manufactured by .....
..... at .....
(Name and address of actual manufacturer)
How stored pending certification .....
.....
(State conditions of storage, with kind and size of containers, location, etc.)
Certification requested of this color for use in
.....
.....
(State proposed uses)
Required fee, $..... (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 8.23 and is accurately representative thereof.

(Signed)
By .....
.....
(Title)

(3) *Request for certification of a repack of a batch of certified color additive.*

Date .....

Color Certification Branch,
Food and Drug Administration,
Department of Health, Education, and Welfare,
Washington 25, D.C.

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive repack.

Name of color .....
(As listed in regulations and as certified; or repacker's name, if a mixture)
Original lot number .....
Certified color content .....
This color obtained from .....
Batch number .....
Batch weighs ..... pounds
How stored pending certification .....
.....
(State conditions of storage, with kind and size of containers, location, etc.)
Certification requested for use in .....
.....
.....
(State proposed uses)
Required fee, $..... (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 8.23 and is accurately representative thereof.

(Signed)
By .....
.....
(Title)

(4) *Request for certification of a batch of color additive mixture.*

Date _____

Color Certification Branch,
Food and Drug Administration,
Department of Health, Education, and Welfare,
Washington 25, D.C.

In accordance with the regulations promulgated under the Federal Food, Drug, and Cosmetic Act, we hereby make application for the certification of a batch of color additive mixture.

Name of mixture _____
(Manufacturer's trade name)

Batch number _____
(Manufacturer's number)

Weight of batch _____ pounds
Volume of batch _____ gallons
(If liquid)

Batch manufactured by _____

Constituents of the mixture:

1. *Certified color(s)* (List separately each color and each lot number.)

Name of color (as certified)	*Lot number*
_____	_____
_____	_____
Quantity used (in pounds)	*Obtained from*
_____	_____
_____	_____

2. List of diluents (List separately each diluent.)

Name of diluent	*Quantity (if liquid)*
_____	_____
_____	_____

Quantity used	
By weight (if liquid)	*By volume (if liquid)*
_____	_____
_____	_____

Batch mixed as follows _____
(Describe in detail)

How stored pending certification _____
_____
(State conditions of storage, with kind and size of containers, location, etc.)

Certification requested for use in _____
_____
_____
(State proposed uses)

Required fee, $____ (drawn to the order of Food and Drug Administration).

The accompanying sample was taken after the batch was mixed in accordance with 21 CFR 8.23 and is accurately representative thereof.

(Signed)
By _____
_____
(Title)

§ 8.23 Samples to accompany requests for certification.

A sample of a batch of color additive which is to accompany a request for certification shall:

(a) Be taken only after such batch has been so thoroughly mixed as to be of uniform composition throughout.

(b) Be closed in a container of such kind as to prevent change in the composition of such sample.

(c) Be labeled to show:

(1) The name of the color.

(2) The manufacturer's batch number.

(3) The quantity of such batch.

(4) The name and post-office address of the persons requesting certification of such batch.

§ 8.24 Treatment of batch pending certification.

Immediately after the sample that is to accompany a request for certification of a batch of color additive is taken, the batch shall be:

(a) Stored in containers of such kind as to prevent change in composition.

(b) Held at place of manufacture until certified or until certification thereof is refused.

(c) Marked, by labeling or otherwise, in a manner such that there can be no question as to the identity of the batch and no question that it is not to be used until the requested certificate has been issued.

§ 8.25 Treatment of batch after certification.

(a) Immediately upon notification that a batch of color additive has been certified, the manufacturer thereof shall identify such batch, by labeling, with the certified lot number and pure color content.

(b) Maintain storage in such manner as to prevent change in composition until such batch has been packaged and labeled as required by §§ 8.31 and 8.32, except that a manufacturer may use such color additive for the purpose of coloring in a food, drug, or cosmetic, or in a mixture in which that color additive is used as an ingredient.

§ 8.26 Records of distribution.

(a) The person to whom a certificate is issued shall keep complete records showing the disposal of all the color additive from the batch covered by such certificate. Upon the request of any officer or employee of the Food and Drug Administration or of any other officer or employee acting on behalf of the Secretary of Health, Education, and Welfare, such person, at all reasonable hours until at least 2 years after disposal of all such color, shall make such records available to any such officer or employee, and shall accord to such officer or employee full opportunity to make inventory of stocks of such color on hand and otherwise to check the correctness of such records.

(b) The records required to be kept by paragraph (a) of this section shall show:

(1) Each quantity used by such person from such batch and the date and kind of such use.

(2) The date and quantity of each shipment or delivery from such batch, and the name and post-office address of the person to whom such shipment or delivery was made.

(c) The records required to be kept by paragraph (a) of this section shall be kept separately from all other records.

§ 8.27 Certification.

(a) If the Commissioner determines, after such investigations as he considers to be necessary, that:

(1) A request submitted in accordance with § 8.22 appears to contain no untrue statement of a material fact;

(2) In the case of a straight color, such color conforms to the specifications set forth therefor in Subpart C, E, or G of this part.

(3) In the case of a mixture, the diluent is safe for use; and

(4) The batch covered by such request otherwise appears to comply with the regulations in this part, the Commissioner shall issue to the person who submitted such request a certificate showing the lot number assigned to such batch and that such batch, subject to the terms, conditions, and restrictions prescribed by Subpart C of this part, is a certified batch.

(b) If the Commissioner determines, after such investigation as he considers to be necessary, that a request submitted in accordance with § 8.22, or the batch of color additive covered by such request, does not comply with the requirements prescribed by paragraph (a) of this section for the issuance of a certificate, the Commissioner shall refuse to certify such batch and shall give notice thereof to the person who submitted such request, stating his reasons for refusal.

§ 8.28 Authority to refuse certification service.

(a) When it appears to the Commissioner that a person has:

(1) Obtained, or attempted to obtain, a certificate through fraud or misrepresentation of a material fact.

(2) Falsified the records required to be kept by § 8.26; or

(3) Failed to keep such records, or to make them available, or to accord full opportunity to make inventory of stocks on hand or otherwise to check the correctness of such records, as required by § 8.26; or

(4) Refused to permit duly authorized employees of Food and Drug Administration free access to all manufacturing facilities, processes, and formulae involved in the manufacture of color additives and intermediates from which such color additives are derived;

he may immediately suspend certification service to such person and may continue such suspension until adequate corrective action has been taken.

(b) Upon receipt of notice of suspension of service, the person so notified may request a hearing upon the factual basis for the suspension. The procedure at the hearing shall conform as nearly as possible to the procedure described in §§ 130.14–130.26 of this chapter.

§ 8.29 Limitations of certificates.

(a) If a certificate is obtained through fraud or misrepresentation of a material fact, such certificate shall not be effective, and a color additive from the batch on which such certificate was issued shall be considered to be from a batch that has not been certified in accordance with the regulations in this part. Whenever, the Commissioner learns that any certificate has been obtained through fraud or material misrepresentation, he shall notify the holder of the certificate that it is of no effect.

(b) If between the time a sample of color additive accompanying a request for certification is taken and the time a certificate covering the batch of such color is received by the person to whom

it is issued, any such color becomes changed in composition, such certificates shall not be effective with respect to such changed color and such changed color shall be considered to be from a batch that has not been certified in accordance with the regulations in this part.

(e) If at any time after a certificate is received by the person to whom it is issued any color additive from the batch covered by such certificate becomes changed in composition, such certificate shall expire with respect to such changed color. After such expiration such color shall be considered to be from a batch that has not been certified in accordance with this part; except that such color shall not be so considered when used for coloring a food, drug, or cosmetic, or for the purpose of certifying a batch of a mixture in which such color was used as an ingredient, if such change resulted solely from such use.

(d) A certificate shall expire with respect to any color additive covered thereby if the package in which such color was closed for shipment or delivery is opened. After such expiration such color shall be considered to be from a batch that has not been certified except that such color shall not be so considered when the package is opened; (1) and such color is used, subject to the restrictions prescribed by paragraphs (f), (g), and (h) of this section, in coloring a food, drug, or cosmetic; (2) for the purpose of certifying a batch made by repacking such color; or (3) for the purpose of certifying a batch of a mixture in which such color is used as an ingredient.

(e) A certificate shall not be effective with respect to a package of color additive and such color shall be considered to be from a batch that has not been certified if such package is shipped or delivered under a label which does not bear all words, statements, and other information required by § 8.32 to appear thereon.

(f) A certificate shall not be effective with respect to a package of color additive, and such color shall be considered to be from a batch that has not been certified if: (1) Such package has not been sealed in accordance with § 8.31; (2) such package has been sealed in accordance with § 8.31 and the seal has been broken, intentionally or accidentally, unless such seal has been broken for the purpose of using color in accordance with § 8.25, or, such package has been opened by a duly authorized representative of the Administration or Department in the performance of his official duties, and he has immediately resealed the package in conformance with § 8.31.

(g) A certificate shall not be effective with respect to a package of color additive and such color shall be considered to be from a batch that has not been certified if such color is used in any manner other than that for which it was certified.

(h) When the listing or the specifications for a color additive are revoked or amended, the final order effecting the revocation or amendment may specify, in addition to its own effective date, a date on which all certificates for existing batches and portions of batches of such a color additive theretofore issued under such revoked or amended regulations shall cease to be effective; and any such lots of the color shall be regarded as uncertified after the date specified unless a new certificate can be and is obtained in conformance with the new regulations. When a certificate thus ceases to be effective for a color additive, any certificates previously issued for a color mixture containing that color shall cease to be effective on the same date. Use of such color or color mixture after such specified date without the new certificate in preparing food, drugs, or cosmetics will result in such food, drugs, or cosmetics being adulterated. When a certified color additive has been used in food, drugs, or cosmetics and the status of the color is thereafter changed by amendment or revocation of its listing or specification regulations, such food, drugs, and cosmetics will not be regarded as adulterated by reason of the use of such color, unless the hazard to health is such that existing stocks of the colored foods, drugs, or cosmetics cannot be safely used, in which cases findings to that effect will be made and regulations appropriate for such special cases will be issued.

§ 8.30 Color additive mixtures that may be certified.

(a) *Color additive mixtures for use in food.* A batch of color additive mixture which contains one or more straight colors listed in Subpart C, E, or G of this part may be certified for use in food, subject to such restrictions as are prescribed in Subparts A and B, if:

(1) Each color additive used as an ingredient in such batch is from a previously certified batch, and such color has not changed in composition in any manner whatsoever since previous certification, except by mixing into such batch of mixture.

(2) Each diluent in such batch of mixture is from the following list:

Sodium chloride (salt).	Olive oil.
Water.	Peanut oil.
Ethanol.	Corn oil.
Propylene glycol.	Cottonseed oil.
Glycerin.	Hydrogenated vegetable oil.
Glucose.	Citric acid.
Sucrose.	Tartaric acid.
Lactose.	Malic acid.
Sorbitol.	Phosphoric acid.
Lecithin.	Tricalcium phosphate.
Starch.	Karaya gum.
Flour.	
Coconut oil.	

(b) *Color additive mixtures for use in coloring shell eggs.* A batch of color additive which contains one or more straight colors listed in Subpart C of this part may be certified for external application to shell eggs, if:

(1) Each color additive used as an ingredient in such batch is from a previously certified batch, and such color has not changed in composition in any manner whatsoever since previous certification, except by mixing into such batch of mixture.

(2) Each diluent contained in such batch of mixture is safe for use on shell eggs.

(c) *Color additive mixtures for use in coloring drugs.* A batch of color additive mixture which contains one or more straight colors listed in Subpart E may be certified for use in drugs, subject to such restrictions as are prescribed in Subparts A and B of this part, if:

(1) Each color additive used as an ingredient in such batch is from a previously certified batch and such color has not changed in composition in any manner whatsoever since previous certification, except by mixing into such batch of mixture.

(2) Each diluent contained in such batch of mixture is safe for use in drugs.

(d) *Color additive mixtures for use in coloring cosmetics.* A batch of color additive mixture which contains one or more straight colors listed in Subpart G may be certified for use in cosmetics, subject to such restrictions as are prescribed in Subparts A and B of this part, if:

(1) Each color additive used as an ingredient in such batch is from a previously certified batch and such color has not changed in composition in any manner whatsoever since previous certification except by mixing into such batch of mixture.

(2) Each diluent contained in such batch of mixture is safe for use in cosmetics.

§ 8.31 Packaging requirements for color additives (other than hair dyes).

Color additives shall be packaged in containers which prevent changes in composition. Packages shall be sealed so that they cannot be opened without breaking the seal. An unavoidable change in moisture content caused by the ordinary and customary exposure that occurs in good storage, packing, and distribution practice is not considered a change in composition.

§ 8.32 Labeling requirements for color additives (other than hair dyes).

(a) *General labeling requirements.* All color additives shall be labeled with sufficient information to assure their safe use and to allow a determination of compliance with any limitations imposed by Subparts A and B of this part. Labels for color additives shall state:

(i) The name of the color additive, as listed in Subpart C, E, or G of this part, if it is a straight color, or the name of each ingredient comprising the color additive, if it is a mixture.

(ii) A statement indicating general limitations for the use of the color additive, such as "for food use only"; "for food, drug, and cosmetic use"; "for use in drugs for external application only."

(iii) The amount of each color in terms of weight per unit volume or percent by weight.

(iv) An expiration date if stability data require it.

(b) *Special labeling for color additives with tolerances.* Where tolerances are imposed for a general or specific use of the color additives by Subparts C, E,

and G, of this part the label shall in addition provide directions for use of the additive which if followed will preclude the food, drug, or cosmetic to which it is added from containing an amount of the color additive in excess of the tolerance.

(c) *Special labeling for color additives with other limitations.* If use of the color additive is subject to other limitations prescribed in this part, such limitations shall be stated on the label of the color additive by a plain and conspicuous statement. Examples of such limitation statements are: "Do not use in products used in the area of the eye"; "Do not use for coloring drugs for injection."

(d) *Special labeling for color additives not exempt from certification.* Color additives not exempt from the certification procedures shall in addition include in the labeling the lot number assigned by the Color Certification Branch, except that in the case of any mixture for household use which contains not more than 5 percent of pure color and which is in packages containing not more than one ounce there appears on the label, a code number which the manufacturer has identified with the lot number by giving to the Food and Drug Administration written notice that such code number will be used in lieu of the lot number.

§ 8.33 Exemption of color additives for investigational use.

A color additive, or a food, drug, or cosmetic containing such an additive, intended for investigational use by qualified experts, shall be exempt from the requirements of sections 402(c), 501(a), or 601(e) of the act, whichever is applicable, provided that the color additive or the food, drug, or cosmetic containing the additive bears a label which states prominently, "Caution—Contains new color additive—For investigational use only."

§ 8.34 Safety factors to be considered.

In accordance with section 706(b)(5)(A)(iii) of the act, the following safety factor will be applied in determining whether the proposed use of a color additive will be safe: Except where evidence is submitted which justifies use of a different safety factor, a safety factor of 100 to 1 will be used in applying animal experimentation data to man; that is, a color additive for use by man will not be granted a tolerance that will exceed 1/100th of the maximum no-effect level for the most susceptible experimental animals.

§ 8.35 General principles of evaluating the safety of color additives.

(a) In reaching a decision on any petition filed under section 706 of the act, the Commissioner will give full consideration to the specific biological properties of the color additive and the adequacy of the methods employed to demonstrate its safety for the proposed use. When considering color additives for food, for drugs, and for cosmetic uses that involve ingestion, the Commissioner will be guided by the principles and procedures for establishing the safety of food additives provided in current publications of the National Academy of Sciences-National Research Council. A petition will not be denied, however, by reason of the petitioner's having followed precedures other than those outlined in the publications of the National Academy of Sciences-National Research Council if, from available evidence, the Commissioner finds that the procedures used give results as reliable as, or more reliable than, those reasonably to be expected from the use of the outlined procedures. In reaching a decision, the Commissioner will give due weight to all levels and patterns of consumption of the additive specified or reasonably to be anticipated. For the purposes of this section, the principles for evaluating safety of additives set forth in the above-mentioned publications will apply to any substance that may properly be classified as a color additive as defined in section 201(t) of the act.

(b) The safety for external color additives shall be determined by tests for acute oral toxicity, primary irritation, sensitization, subacute dermal toxicity on intact and abraded skin, and carcinogenicity by skin application.

(c) Upon written request describing the proposed use of an additive and the proposed experiments to determine its safety, the Commissioner will advise a person who wishes to establish the safety of a color additive whether he believes the experiments planned will yield data adequate for an evaluation of the safety of the additive.

§ 8.36 Application of the anti-cancer clause of section 706 of the act.

(a) *Color additives that may be ingested.* Whenever the scientific data before the Commissioner (either the reports from the scientific literature or the results of biological testing) suggest the possibility that the color additive or any of its components or impurities has induced cancer when ingested by man or animal, the Commissioner shall determine whether, based on the best judgment of appropriately qualified scientists, cancer has been induced and whether the color additive or any of its components or impurities was the causative substance. If it is his best judgment that the data do not establish these facts, the anti-cancer clause is not applicable; and if the data considered as a whole establish that the color additive will be safe under the conditions that can be specified in the regulation, it may be listed for such use. But if, in the best judgment of the Commissioner, based on information from qualified scientists, cancer has been induced by ingestion, no regulation may issue which permits its use.

(b) *Color additives that will not be ingested.* Whenever the scientific data before the Commissioner suggest the possibility that the color additive or any of its components or impurities has induced cancer in man or animals by routes other than ingestion, the Commissioner shall determine whether, based on the best judgment of appropriately qualified scientists, the test suggesting the possibility of carcinogenesis is appropriate for the evaluation of the color additive for a use which does not involve ingestion, cancer has been induced, and the color additive or any of its components or impurities was the causative substance. If it is his best judgment that the data do not establish these facts, the anti-cancer clause is not applicable to preclude external drug and cosmetic uses, and if the data as a whole establish that the color additive will be safe under conditions which can be specified in the regulations, it may be listed for such use. But, if, in the best judgment of the Commissioner based on information from qualified scientists the test is an appropriate one for the consideration of safety for the proposed external use, and cancer has been induced by the color additive or any of its components or impurities, no regulation may issue which permits its use in external drugs and cosmetics.

§ 8.50 Fees.

(a) Each petition or request for the listing of a color additive shall be accompanied by a deposit of $3,000.00 if the proposal is for listing the color additive for use generally in or on foods, in or on drugs, and in or on cosmetics.

(b) If the petition or request for the listing is for use in or on foods only, the deposit shall be $3,000.00.

(c) If the petition or request for the listing is for use in or on drugs and/or cosmetics only, the deposit shall be $2,600.00.

(d) The provisions of paragraphs (a), (b), and (c) of this section shall be applicable, whether or not the proposal contemplates any tolerances, limitations, or other restrictions placed upon the use of the color additive.

(e) If a petition or request proposing the issuance of a regulation is withdrawn before it is finally accepted for filing, the deposit, less a $600.00 fee for clerical handling and administrative and technical review, shall be returned to the petitioner.

(f) If a petition or a request proposing the issuance of a regulation is withdrawn within 30 days after filing, the deposit, less $1,800, if the petition is covered by paragraph (a) or (b), and less $1,600.00, if the petition is covered by paragraph (c), shall be returned to the petitioner.

(g) When a petition is withdrawn after filing and resubmitted within 6 months, it shall be accompanied by a deposit of $1,800.00 for a petition filed under paragraph (a) or (b), and $1,600.00 for a petition filed under paragraph (c) of this section. If a petition is resubmitted after 6 months, it shall be accompanied by the deposit that would be required if it were being submitted for the first time.

(h) When the resubmission pertains to a petition that had been withdrawn before acceptance for filing, a new advance deposit shall be made in full as prescribed in paragraph (a), (b), or (c) of this section.

(i) After a color has been listed, any request for an amendment or additional tolerance shall be accompanied by a

deposit of $1,800.00 for use in the items specified in paragraphs (a) and (b) of this section, or $1,600.00 for use in items specified in paragraph (c) of this section.

(j) Objections and request for public hearing under section 706(d) or 203(d)(2)(C) of the act shall be accompanied by a filing fee of $250.00.

(k) In the event of a referral of a petition under this section to an advisory committee, all costs related thereto (including personal compensation of committee members, travel materials, and other costs) shall be borne by the person or organization requesting the referral, such costs to be assessed on the basis of actual cost to the Government: *Provided*, That the compensation of such costs shall include personal compensation of advisory committee members at a rate not to exceed $75.00 per member per day.

(l) In the case of requests of referrals to advisory committees, a special advance deposit shall be made in the amount of $2,500.00. Where required, further advance in increments of $2,500.00 each shall be made upon request of the Commissioner of Food and Drugs. All deposits for referrals to advisory committees in excess of actual expenses shall be refunded to the depositor.

(m) All requests for pharmacological or other scientific studies shall be accompanied by an advance deposit of $5,000.00. Further advance deposits shall be made upon request of the Commissioner of Food and Drugs when necessary to prevent arrears in such costs. Any deposits in excess of actual expenses will be refunded to the depositor.

(n) The person who files a petition for judicial review of an order under section 706(d) of the act shall pay the costs of preparing a transcript of the record on which the order is based.

(o) All deposits and fees required by the regulations in this section shall be paid by money order, bank draft, or certified check drawn to the order of the Food and Drug Administration, collectible at par at Washington, D.C. All deposits and fees shall be forwarded to the Food and Drug Administration, Department of Health, Education, and Welfare, Washington 25, D.C., whereupon after making appropriate record thereof they will be transmitted to the Treasurer of the United States for deposit in the special account "Certification, Inspection, and Other Services, Food and Drug Administration."

(p) The Commissioner of Food and Drugs may waive or refund such fees in whole or in part when in his judgment such action will promote the public interest.

(q) Any person who believes that payment of these fees will work a hardship on him may petition the Commissioner of Food and Drugs to waive or refund the fees.

Subpart B—General Specifications and General Restrictions for Color Additives for Use in Foods, Drugs, and Cosmetics

§ 8.101 General restrictions on use of color additives.

(a) *Color additives for use in the area of the eye.* (1) No listing or certification of a color additive shall, except as provided by subparagraph (2) of this paragraph, be considered to authorize the use of any color additive in any article intended for use in the area of the eye. A color additive used or any such article that is applied to the area of the eye, except as provided by subparagraph (2) of this paragraph, shall be considered to be a color additive not listed under Subparts D and E, even though such color is certified and/or listed for other uses.

(2) Color additives, if listed and certified or exempted from certification for such uses, pursuant to specifications in this part, may be used in the area of the eye for the following purposes:

(i) For absorbable and nonabsorbable ophthalmological suture material.

(ii) Eye shadow.

[Paragraph (b) reserved]

Dated: January 16, 1961.

[SEAL] GEO. P. LARRICK,
Commissioner of Food and Drugs.

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